MAY 3 0 2012

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 892.2050.

Submitter:	Materialise Dental NV Technologielaan 15 Leuven Belgium
Establishment Reg. Number:	3006638827
Contact:	Carl Van Lierde QARA Management Representative Materialise Dental NV Technologielaan 15 Leuven Belgium Tel. +32 16 39 6620 Fax. +32 16 39 66 22 Email: Carl.VanLierde@materialise.be
Date Prepared:	November 29, 2011
Trade/ Proprietary Name:	**SimPlant Immediate Smile System**
Common/Usual Name:	System, Image processing. The product uses images acquired from Computerized Tomography (CT) scanners
Classification Name/ FDA Reviewing Branch:	Picture Archiving and Communication system
Device Classification/ Code:	Class II - 21 CFR §892.2050 LLZ

Predicate Device Manufacturer:	SimPlant® 2011; (K110300) Nobel Biocare Guided Surgery Concept; (K050393) Ivoclar_Vivadent - Telio CAD (K093708)
Purpose of the 510(k) notice:	The reason for this 510k submission is to request clearance for a device that has been referred to herein as SimPlant Immediate Smile System (Image processing system) referenced under 21 CFR §892.2050 and considered a Class II device.
Device Description:	The **SimPlant Immediate Smile System** is intended for use in treatment planning and placement of dental implants, in order to restore masticatory function.The **SimPlant Immediate Smile System** enables a predictable dental implant restoration procedure according to case planning done by the clinician. The **SimPlant Immediate Smile System** enables a provisional prosthesis to be produced prior to and attached in the same session as implant installation. The **SimPlant Immediate Smile System** includes SimPlant software that provides a method of importing medical imaging information from radiological imaging systems such as a Computer Tomography (CT) or Magnetic Resonance Imaging (MRI) to a computer file that is usable in conjunction with other diagnostic tools and expert clinical judgment. Visual representations of the imaged anatomical structures (e.g. the jaw) are derived, allowing for a three-dimensional assessment of the patient without patient contact. SimPlant enables the clinician to plan the dental implant positions including orientations pre-operatively in a virtual, 3D environment. The case planning can be used to produce patient specific SurgiGuide guides, thus transferring the virtual case planning into physical tools enabling the intra-operative preparation of the implant sites for the installation of implants in accordance to the virtual case planning. The **SimPlant Immediate Smile System** is based upon knowledge of the locations and orientations of the implants prior to surgery. This knowledge enables the production of a SurgiGuide surgical guide. Aided by the SurgiGuide surgical guide, the implant sites can be prepared and the dental implants placed in the predetermined locations, enabling the immediate installation of the custom-made prefabricated provisional Immediate Smile bridge.
Indications for Use:	The **SimPlant Immediate Smile System** is intended for use in treatment planning and placement of dental implants, in order to restore masticatory function.

Technological Characteristics :	The predicate devices, SimPlant® 2011, Nobel Biocare Guided Surgery Concept and Ivoclar – Telio CAD have a number of very similar and equivalent design /technological characteristics, which are very similar and equivalent with the SimPlant Immediate Smile System (see Substantial Equivalence comparison table in Section 14).
Performance Data:	Software Validation in addition to bench top performance testing was conducted to ensure the compatibility of all system components.
Clinical Data:	The SimPlant® Immediate Smile System was evaluated in a clinical setting by 11 doctors from different countries. The System was evaluated with 20 patients. 6 different implant brands were used during the evaluation. Case follow-up was done after 12 weeks. Clinical feedback was gathered for all cases relative to the usability, aesthetic result and adequacy of the material properties of the system components. Predefined acceptance thresholds were met for all criteria indicative for the system safety and effectiveness. The immediate smile bridge component of the System can be used as a temporary restoration for immediate loading up to 12 weeks. The results of the clinical validation confirmed safety and effectiveness of the System.
Non clinical testing	Several Engineering tests and evaluations were undertaken to demonstrate the conformity of the system: • The software is thoroughly tested in accordance with documented test plans and in accordance to internal software development and testing procedures. This test plan is derived from the specifications and ensures that all controls and features are functioning properly. The software is validated together with end-users. The subsequent testing to validate the mitigations was documented in software test reports. • The minimal dimension of the cylindrical connections of the immediate smile bridge where determined based on the maximal load that should be withstood without risk of fracture of the bridge. • In order to evaluation the potential micro-movement of the implants upon loading of the immediate smile bridge component a predictive (mass-spring/ finite element) model was used. Micro-movement is a risk factor for implant failure. With bite load (point load) of 400 N on bridges without distal extension, predicted movements were shown to be acceptable. • Evaluation of cement bonding was conducted via pull-out testing of cylindrical abutments fixed by means of the standard composite into a cylindrical hole corresponding in dimensions with the cylinders incorporated in the design of the provisional restoration. With a average maximal tensile force of 232N and a minimal measured tensile force of 190 N, the threshold of 150 N was exceeded.

<table>
<tr><td></td><td>Based on the performance data the SimPlant Immediate Smile System was demonstrated to be safe and effective, testing all pre-set criteria on component and System levels.</td></tr>
<tr><td>Performance Standards:</td><td>DICOM NEMA PS 3.1-3.18: Digital imaging and communication in medicine: 2009
ISO14971: Applications of risk management to medical devices: 2007
ISO 13485: Medical devices Quality Management System: 2003
ISO10993: Biological evaluations of medical devices: 1992</td></tr>
<tr><td>Technological Characterisitics:</td><td>Materialise Dental NV's SimPlant Immediate Smile System included in this submission uses the same fundamental scientific technology as the previously cleared SimPlant® 2011; (K110300).
<table>
<tr><th></th><th>Device for premarket notification</th><th>K110300</th></tr>
<tr><td>Trade name</td><td>SimPlant® Immediate Smile System</td><td>SimPlant® 2011</td></tr>
<tr><td>Material</td><td>Software – Magnetic media

Hardware –
• acrylic guides – biocompatible material
• stainless steel tubes/sleeves – medical grade
• PMMA provisional bridges – biocompatible</td><td>Software – Magnetic media</td></tr>
</table></td></tr>
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	Design	Software for use in pre-operative planning. The **SimPlant Immediate Smile System** includes **SimPlant® software**, which provides a means for the clinician for image segmentation and advanced pre-operative planning. This enables the clinician to view three-dimensional CT-scan data as well as to plan the case in a virtual three-dimensional environment. This case planning can be used to produce a Surgical Template, thus transferring the virtual case planning into physical tools enabling the surgical installation according to the virtual case planning. The **SimPlant Immediate Smile System** is based upon knowledge of the location and orientation of the implant(s) prior to the surgery. This knowledge enables the production of a SurgiGuide. Aided by the SurgiGuide, the sites can be prepared and the implants placed in the predetermined locations enabling the immediate attachment of the prefabricated temporary prosthesis, i.e. the **Immediate Smile** bridge structure or final prosthesis.	Software for use in pre-operative planning. **SimPlant® software** provides a means for image segmentation and advanced pre-operative planning. Surgical templates may be fabricated based on the output of the pre-operative planning.

	Function	The **SimPlant® software** component is used to incorporate the images from either an MRI or CT scan of the affected joint into the specialized planning software. The **SimPlant® software** is used by a qualified surgeon to plan, inspect, fine-tune and approve the pre-surgical plan. The software is used pre-operatively. **SimPlant® software** contains a library of dental implants, and additional instruments for the placement of implants. A **SurgiGuide® guide** and/or **Immediate Smile Provisional** bridge structures may be designed and fabricated based on the output of the pre-operative planning. **SurgiGuide® guides** are patient specific templates that are intended to transfer the pre-operatively determined positioning of the dental implants to the patient intra-operatively, assisting the surgeon in placing dental implants by guiding and marking drill locations. The **Immediate Smile** bridge structure is a patient specific temporary restoration, for partially or fully edentulous cases either in lower or upper jaw, to be used immediately after implant placement and this for a short term, i.e. maximally 16 weeks.	**SimPlant® software** is used to incorporate the images from either an MRI or CT scan of the affected joint into the specialized planning software. The **SimPlant® software** is used by a qualified surgeon to plan, inspect, fine-tune and approve the pre-surgical plan. The software is used pre-operatively. **SimPlant® software** contains a library of dental implants, and additional instruments for the placement of implants. A **SurgiGuide® guide** may be designed and fabricated based on the output of the pre-operative planning.
	Programming language	C++	C++
	Operating system	Windows	Windows

The SimPlant Immediate Smile brigde resin, included in this submission uses the same fundamental scientific technology and has similar indications and principles of operation as the previously cleared Telio CAD resin; (K093708).

		Device for premarket notification	K093708
	Trade name	**SimPlant® Immediate Smile Bridge resin**	**Ivoclar – Telio CAD**
	Material Chemical Characteristics	100 % PMMA (Polymethylmethacrylat)	99.5 % Polymethylmethacrylate (CAS-No. 9011-14-7), Pigments
	Mechanical Characterisitics	Flexural strength 97 MPaHardness 145 MPa Water absorption 21 µg/mm³ Water solubility 1,1 µg/mm³	Flexural strength 130 MPa Hardness 180 MPa Water absorption < 28 µg/mm³ Solubility in water < 0.6 µg/mm³
	Biocompatibility	Biocompatibility of the dental prosthesis material were performed according to the international standards ISO 10.993-1992 "Biological evaluation of medical devices" (ISO 10993-1, ISO 10993-5, ISO-DIS 10993-10) and DIN-V 13 930-1990 "Biological test of dental materials". The resin did not have any cell toxic potential The resin did not cause any irritation of the skin or any allergic sensitisation.	Test specimens made of Telio CAD were subjected to cytotoxicity and mutagenicity tests. The results of both tests show that Telio CAD is neither cytotoxic nor mutagenic and that its use does not pose a toxicological risk if used as indicated in the respective instructions for use.
	Storage	To be stored in the original packaging, in a dry environment (< 25 °C), away from direct sunlight. Shelf life 4 years.	No specific requirements. Store at 2-28 °C / 36-82 °F
	Wear period	Up to 6 months. (i.e. longer than recommended life of the SimPlant Immediate Smile bridge)	12 months
Conclusion:	SimPlant Immediate Smile System and its predicate devices, SimPlant® 2011 (K110300), the Nobel Biocare Guided Surgery Concept (K050393) and Ivoclar Telio CAD, have the same technological characteristics and principles of operation. The SimPlant Immediate Smile System can be used with SurgiGuide® guides and / or with provisional Immediate Smile bridges. SurgiGuide® guides are patient specific templates used intra-operatively to prepare the osteotomy for placement of dental implants, manufactured as pre-operatively determined in the software. SurgiGuide guides for upper and/or lower jaw are designed and manufactured using rapid prototyping (stereolithography), based on the approved pre-surgical implant plan. Immediate Smile bridges sare patient specific restoration		

	structures, used immediately after implant placement and manufactured in accordance to the pre-operatively determined implant plan in the software. The differences noted above do not present new issues of safety or effectiveness for the SimPlant® Immediate Smile System.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Carl Van Lierde
QARA Management Representative
Materialise Dental NV
Technologielaan 15
B-3001 LEUVEN
BELGIUM

MAY 30 2012

Re: K113739
Trade/Device Name: SimPlant® Immediate Smile System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ, DZE, and EBG
Dated: May 25, 2012
Received: May 29, 2012

Dear Mr. Lierde:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113739

Device Name: **SimPlant® Immediate Smile System**

Indications for Use:

The **SimPlant Immediate Smile System** is intended for use in treatment planning and placement of dental implants, in order to restore masticatory function.

Prescription Use ___X___ **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) **AND/OR** **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113739